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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,582	10/05/2001	Sarvajit Chakravarty	219002028402	4932

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/06/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,582

Applicant(s)

CHAKRAVARTY ET AL.

Examiner

Hong Liu

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8-10,13,15-20 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8-10,13,15-17,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1624

DETAILED ACTION

Claims 1, 8-10, 13, 15-20, and 23-33 are pending in this application.

Response to Arguments

Applicants' arguments filed on May 14, 2003 have been fully considered with the following effect:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action dated April 24, 2000.

Election/Restriction

It is noted that applicants have canceled the non-elected subject matter: claims 21 and 22. However, similar non-elected subject matter, claims 18-20 and 25-33 has not been canceled.

Claim Rejections - 35 USC § 112

The Rejection under 35 U.S.C. 112, First paragraph

Claims 1, 8-10, 13, 15, and 17 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. The Examiner in this case has provided both "evidence" and "reasoning" to cast doubt on the sufficiency of enablement

Art Unit: 1624

provided in the instant closure. See rejection made in the previous Office Action and those maintained below.

The claims are still not commensurate in scope as to the diversity of Markush groups embraced by the definitions of "a divalent moiety that provides a distance of 2-8A between ring B and Ar'," which all permit further substitution on the bicyclic ring. The instant case is similar to *In re Lund*, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. Applicants urge that the compounds embraced herein are active as p38 alpha antagonists, and thus all of the functional moieties and a divalent moiety that provides a distance of 2-8A between ring B and Ar' which are embraced by these claims have the activity of inhibiting . However, no reasons or evidence has been provided to support applicants' position. As was previously mentioned, there is no showing in the specification that any divalent moiety meeting the requirement of 2-8A have anti-p38 alpha activity. Thus, applicants have not provided adequate information that the instant compounds **as an entire class** have the required activities needed to practice the invention, and therefore, there is no reasonable basis for assuming that the variety of substituents embraced by the claims will all share the same physiological properties. See MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Note also the quote taken from *Surrey*, previously cited, "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" these compounds either." Also note the quote taken from *In*

Art Unit: 1624

re Cavallito 127 USPQ 202 which was cited in Surrey, previously cited, at page 730; "...where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful...An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." Note Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See In re Fouche, 169 USPQ 429. Furthermore, applicants rely on the working examples listed in the variety of Tables in the specification, but as mentioned before, these examples are limited to a homogenous group of compounds. The specification is silent as to the availability of the necessary starting materials needed for preparing all polyfused aryls and heteros of varying fusion and size at one or more location on the purine ring system. Note In re Armbruster, 185 USPQ 152, wherein it was stated that a specification which "describes the invention as broadly as it is claimed...does not necessarily also "enable" one skilled in the art to make or use the claimed invention."

The Rejections under 35 U.S.C. 112, Second paragraph

5). Rejection of the previous Office Action under 35 U.S.C. 112, second paragraph, is maintained for reasons already made of record. As stated, the term "cyclic aliphatic" and

Art Unit: 1624

“heteroaliphatic” do not specify the ring systems, heteroatoms, etc. See *In re Wiggins* 179 USPQ 421 for certain terminology regarding heterocyclic ring systems. Applicants’ amendment of the term to “cyclic hydrocarbyl aliphatic” is even more confusing. First, there is no definition for the term in the specification. The term is thus open-ended and all encompassing. Second, it is not understood why there are two “cyclic hydrocarbyl aliphatic” phrases in the same sentence (see p. 37). What is the difference between these two phrases?

All other rejections under 35 U.S.C. 112, second paragraph, are hereby withdrawn in view of applicants’ amendment and arguments.

For the reasons given above, claims 1, 8-10, 13, 15-17 remain rejected and claims 25-29 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The rejection of claims 1 and 8-10 under 35 USC 102(b) is hereby withdrawn in view of applicants’ amendments and arguments.

Claim Rejections - 35 USC § 103

1. Claims 1, 8-10, 13, and 15 remain rejected and claims 23, 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alvi et al. (WO 99/18942). Applicants argued that the present application is entitled to the priority date of application No. 09/141,916, filed on August

Art Unit: 1624

28, 1998 which was prior to the publication date of the reference, April 22, 1999. However, application 09/141,916 does not disclose that L can be a divalent moiety that provides a distance of 2-8A between ring B and Ar'. Nor does it disclose that Z5, Z6, and Z7 can be both N and CR2. Since the parent application cannot lend support for the present application, the present application is not entitled to the priority date for the purpose of avoiding the art rejection.

Double Patenting

The rejection of claims 1, 8-10, 13, 15-17, 23, and 24 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of U. S. Patent No. 6,476,031 and claims 1-8 of US Patent No. 6,184,226 is maintained. The terminal disclaimers applicants mentioned in the response are disclaimers for patents 6,476,031 and 6,184,226, which are inapplicable to the present application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1624

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for **official** business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu
June 2, 2003


Mukund Shah
Supervisory Patent Examiner
Art Unit 1624